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7278 7590 07/27/2007 DARBY & DARBY P.C. P.O. BOX 770 Church Street Station New York, NY 10008-0770			EXAMINER BAUSCH, SARAE L	
			ART UNIT 1634	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/817,102

Applicant(s)

CAUFIELD ET AL.

Examiner

Sarae Bausch

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-29 and 32-36 is/are pending in the application.
- 4a) Of the above claim(s) 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5-16,22-27,29 and 32-36 is/are rejected.
- 7) ☒ Claim(s) 4, 17-21, 29, 32-36 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Currently, claims 1, 3-29, and 32-36 are pending in the instant application. Claims 2 and 30-31 have been canceled. Claims 1, 3-4, 6-7, 25-26, 29, 32-36 has been amended while claim 28 is withdrawn. This action is written in response to applicant's correspondence submitted 05/04/2007. All the amendments and arguments have been thoroughly reviewed but were found insufficient to place the instantly examined claims in condition for allowance. The following rejections are either newly presented, as necessitated by amendment, or are reiterated from the previous office action. Any rejections not reiterated in this action have been withdrawn as necessitated by applicant's amendments to the claims. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. **This action is Final.**

Withdrawn Objections/Rejections

2. The objection to the specification, made in section 10, page 4 of the previous office action mailed 10/11/2006, is withdrawn in view of the amendment to the specification.
3. The objection to claim 4, made in section 11, page 5 of the office action mailed 10/11/2006, is withdrawn in view of the amendment to the claim.
4. The rejections of claims 1-27, under 35 U.S.C. 112, second paragraph, made in section, 13 (a), page 5 of the previous office action mailed 10/11/2006, is withdrawn in view of the amendment to the claims.

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5. The rejections of claims 1-27, under 35 U.S.C. 112, second paragraph, made in section, 13 (a), page 5 of the previous office action mailed 10/11/2006, is withdrawn in view of the amendment to the claims.
6. The rejection of claims 7-9, under 35 USC 112, second paragraph, made in section 13(b), page 5 of the previous office action mailed 10/11/2006 is withdrawn in view of the amendment to the claims.
7. The rejection of claims 4, 6, 17-21, and 29-36 under 35 USC 112, second paragraph made in section 13, page 5 of the previous office action mailed 10/11/2006 is withdrawn in view of applicants assertions on page 11 of the response mailed 05/04/2007.
8. The rejection of claims 1, 12-13, 15-17, 19-21, 29, and 31 under 35 USC 102(b), made in section 16, page 8 of the previous office action mailed 10/11/2006 is withdrawn in view of the amendment to the claims.

Claim Amendments

9. It is noted that claim 7 does not comply with 37 CFR 1.121, as it recites a “The method of surveillance of claim 2 1” in line 1 of the claim and the previously presented claim recited “The method of surveillance of claim 6” . Claim 7 originally depended from claim 6 and now depends from claim 1, however the amendment filed 05/04/2007 does not reflect that claim 7 depended from claim 6. In response to this office action, applicant is required to include the appropriate markings to reflect any additions or deletions to the text of the claim.

Maintained Rejections

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1, 3, 11-16, and 22-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Cordery et al. (US 6613571, filed Dec 19, 2001).

With regard to claim 1, Cordery et al. teach a method for detecting biological hazards in mail at point of entry (see column 2, lines 54-58). Cordery et al. teach assaying incoming mail for the presence of biological agents (see column 4, lines 59-65).

With regard to claim 3, 11, Cordery et al. teach assaying incoming mail for the presence of biological agents. Incoming mail can be collected from mailboxes situated on public streets (predetermined pattern and brought to central location, claim 11) (see column 2, lines 63-67 and claim 11 of '571) therefore the mail that is collected by Cordery et al. is from a route undertaken by a street sweeper machine and is a predetermined traceable route.

With regard to claim 12-16, Cordery et al. teach collecting the mail (collected in a predetermined pattern and brought to central location, claim 12) and detecting hazardous mail by

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importing the mail piece into a segregated mail sample, collecting air samples, testing the air sample for hazards, if a hazard is present (increase in level of biological agent) then the process ends if no hazard is present (decreases in level of biological agent) then the mail pieces are transported to a collection chamber (see column 7, lines 13-25).

With regard to claim 22-24, Cordery et al. teach collecting the mail and detecting hazardous mail by collecting air samples from the mail (collection integrity is preserved and assaying a sample is from within the collection bin). Cordery et al. teach that if a hazard is present then the process ends (in communication with collection bin) (see column 7, lines 13-25).

With regard to claim 25-27, Cordery et al. teach detecting hazards in mail using incoming mail receptacle (collection bin), detecting the presence of mail piece collecting air samples, testing air samples for hazards by PCR or UV detection and determining if a hazard is present in the mail (see claim 11 of '571, column 5, lines 23-40 and column 7 lines 13-25).

Response to Arguments

12. The response traverses the rejection on pages 12 of the response mailed 05/04/2007. The response asserts that the mere possibility that mail be collected from a public streets which in turn may be in close proximity to a route undertaken by a street sweeper is not sufficient to inherently teach this limitation of a "route undertaken by a street sweeper machine". The response asserts that there are many mail collection locations that do not include routes undertaken by a street sweeper machine and there are many areas in which street sweeper machines operate that are not served by the Postal Server (modified versions used within buildings). This response has been thoroughly reviewed but not found persuasive. The specification on page 7, lines 5-8, defines a street sweeper as a machine that cleans and/or

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collects trash from streets, sidewalks, floors, promenades, thoroughfares, depots, or other places where people gather. Based on the definition of a street sweeper in the specification, a route undertaken by a street sweeper would encompass any street, which would also encompass a mail route even in rural areas. Furthermore, Cordery et al. teach incoming mail is collected in a central location (see column 2 lines 63-67), which is a depot, and would include a route undertaken by a street sweeper as defined in the specification.

The response asserts that claims 25 and 26 recite a sample that comprises “debris or fluids that result from rinsing an instrumentality used in a collection of materials from a sample domain”. The response asserts that the mail in Cordery is not rinsed. This response has been thoroughly reviewed but not found persuasive. Cordery et al. teach obtaining air sample from mail samples (collection of materials from a sample domain). Cordery et al. teach the sampled air is forced into water (comprises debris or fluid that results from rinsing instrumentality) (see column 5, lines 29-31 and 41-43) therefore Cordery et al. teach fluid that results from rinsing instrumentality used in a collection of materials from a sample domain as Cordery et al. teach rinsing the air sample by forcing the air into water.

13. Claims 1, 3, 5-16 and 22-27 rejected under 35 U.S.C. 102(a) as being anticipated by Hoffmaster et al. (Emerging Inf. Diseases, 2002, Vol 8, No. 10, supplement, p. 1-12).

With regard to claim 1, 3, 6-11, and 22-24, Hoffmaster et al. teach evaluation and validation of RT-PCR for identification of *Bacillus anthracis* in environmental samples (See page 1, 2nd paragraph). Hoffmaster et al. teach elution of swab specimens and environmental samples in a aqueous solution (collection integrity is preserved, claim 22) (claim 10) (see page 2, last paragraph cont'd to page 3). Hoffmaster et al. teach a wide variety of samples were tested

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including vacuum cleaner debris (sample derived from a street sweeper machine, claim 3, 6-9, 11) (sample from within a collection bin, claim 23-24) (see Real-time PCR in environmental samples, page 5).

With regard to claim 5, Hoffmaster et al. teach real-time PCR to detect *B. anthracis* (see page 1, 2nd full paragraph).

With regard to claim 12-16, Hoffmaster et al. teach testing the environmental sample by PCR and culture to determine the presence of *B. anthracis*. Hoffmaster teaches that 35 samples were positive by both methods and only 7 were positive by culture only, 4 positive by PCR only (see Real-time PCR in environmental samples, page 5 and page 7, last two paragraphs).

Therefore, Hoffmaster, teaches assaying for the presence of a biological agent by comparing the level to a normal level (claim 12-14) (positive result in either PCR or culture). Hoffmaster teaches assaying for an increase or decrease relative to an earlier assay (claim 15-16) (PCR versus culture assay).

With regard to claim 25-27, Hoffmaster et al. each testing environmental samples by PCR by elution of swab specimens and environmental samples in an aqueous solution (see page 2, last paragraph con't to page 3). Hoffmaster et al. teach testing the environmental specimens by real time PCR for the detection of *B. anthracis* (biological agent) (see real time PCR of environmental specimens, page 5). Hoffmaster et al. teach reporting the results of the PCR analysis of the samples (see page 5 and page 7).

Response to Arguments

14. The response traverses the rejection on pages 13-14 of the response mailed 05/04/2007. The response asserts that claim 1 require that materials are collected in a pre-existing operation,

otherwise unrelated to surveillance. The response asserts that Hoffmaster obtains environmental samples during the course of an already confirmed outbreak and therefore the samples were not collected in a pre-existing operation, otherwise unrelated to surveillance. This response has been thoroughly reviewed but not found persuasive. The claims are not limited to surveillance occurring only when an outbreak has not occurred nor do are the claims limited to a surveillance in which an outbreak has not been confirmed, the claims merely recite that at least one collection point from which the materials are collected in a pre-existing operation otherwise unrelated to surveillance. The claims are not limited to all samples collected during a pre-existing operation unrelated to surveillance. Hoffmaster et al. teach obtaining environmental sample throughout the United States (see page 2, last paragraph). Hoffmaster et al. teach 140 environmental samples from vent filters, HVAC filters and vacuum cleaner debris were tested (see pg. 5, real-time PCR in environmental samples). The vacuum cleaner was used originally for cleaning and not for the detection anthrax and therefore is a collection technique that was part of a pre-existing operation, cleaning floors and was tested during the outbreak for the presence of anthrax. Therefore, the vacuum cleaner debris was collected in a pre-existing operation, cleaning of floors, which was unrelated to the outbreak of anthrax. Hoffmaster does not teach that vacuum cleaner was used to clean the anthrax outbreak.

The response asserts that Hoffmaster does not disclose rinsing collection bins used to collect materials from a sample domain. The response asserts that the elution of the swab specimens does not disclose or suggest a sample that includes debris or fluid that result from rinsing collection bins used to collect materials. The response asserts that vacuum cleaner is used to collect debris specifically for the Anthrax assay and there is no disclosure of rinsing a

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collection bin associated with the vacuum cleaner. This response has been thoroughly reviewed but not found persuasive. Hoffmaster does not teach that the vacuum cleaner is used solely to collect debris specifically for the Anthrax assay. Hoffmaster et al. teach assaying environmental specimens from a wide variety of samples including vent filters, HVAC filters, paper towels, vacuum clean debris, however Hoffmaster et al. does not teach that these specimens were used solely for the collection of anthrax. Hoffmaster et al. does teach rinsing collection bins by teaching elution of swab specimens of surface specimens, which encompasses sample comprises debris or fluid that result from rinsing an instrumentality used in collection of materials from the sample domain, the swab being used to collect materials from the sample domain and rinsing the instrumentality, the swab specimen (see page 2, last paragraph con't to page 3).

The response asserts that Hoffmaster does not teach a sample domain that includes collection of materials on a regular systematic basis through a predetermined traceable route converging on a centralized location. The response asserts that the collection of environmental samples in Hoffmaster was solely in response to an Anthrax outbreak. The response asserts that Hoffmaster does not teach or suggest collection of materials on a regular, systematic basis nor a predetermined traceable route converging on a centralized location. This response has been thoroughly reviewed but not found persuasive. Hoffmaster et al. teach environmental samples were tested for the presence of Anthrax, however Hoffmaster does not teach nor suggest that the environmental samples that were collected were solely in response to an anthrax outbreak. Hoffmaster does not teach that the HVAC filters, vent filters, dust or vacuum debris was solely collected for anthrax detection. Furthermore, vacuum cleaner debris, vent filter and HVAC filter are all collections that are on a predetermined traceable route and converge to a centralized

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location, collection of the filter or vacuum cleaner debris. Therefore, Hoffmaster et al. anticipates the claimed invention.

For these reasons, and the reasons made of record in the previous office actions, the rejection is maintained.

Conclusion

15. Claims 4, 17-21, 29, 32-36 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

16. No claims are allowable.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarae Bausch whose telephone number is (571) 272-2912. The examiner can normally be reached on M-F 9am-5pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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Sarae Bausch, PhD
Examiner
Art Unit 1634


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PRIMARY EXAMINER
7/23/07